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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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J. Dean Cole

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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

04/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/799,179

Applicant(s)

COLE, J. DEAN

Examiner

Anu Ramana

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3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 38-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,18,23,41-44 and 47-51 is/are allowed.
- 6) ☒ Claim(s) 1-16,19-22,38-40,45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/3/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the article written by Karladani et al. (see attached copy of article).

Karladani et al. disclose insertion of an intramedullary nail or "fixation member" in a tibia by gaining supra patellar surgical access (Fig. 3 and page 737).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 11, 13, 19, 21, 38-40, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karladani et al. in view of Myers (US 5,624,447).

Karladani et al. discloses all elements of the claimed invention except for the use of a protective sheath.

Myers teaches the use of a surgical tool guide and entry hole positioner to access the intramedullary canal of bones while minimizing soft tissue injury (Figs. 1-6, col. 1, lines 4-9, col. 2, lines 31-42 and col. 4, lines 18-58). Myers also teaches the use of a flexible reamer to ream the intramedullary canal to a size large enough to receive the fracture fixation rod (col. 6, lines 48-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the Myers tool guide for placement of the intramedullary nail of the method of Karladani et al., in order to minimize soft tissue injury.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karladani et al. and Myers (US 5,624,447) further in view of Asfora (US 6,419,678).

The combination of Karladani et al. and Myers discloses all elements of the claimed invention except for protrusions or teeth on the distal end of the sheath.

Asfora teaches providing teeth or protrusions on the distal end of a guide or protective device to secure the guide against a bone surface (col. 4, lines 37-47).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided teeth as taught by Asfora on the distal end of the sheath in the device of the method of the combination of Karladani et al. and Myers to secure the sheath against the bone surface.

The method steps of claim 7 are rendered obvious by the above discussion.

Claims 10, 12, 14-16 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karladani et al. in view of Leu et al. (US 6,270,499).

Karladani et al. discloses all elements of the claimed invention except for a particular type of intramedullary fixation device.

Leu et al. teach insertion of an intramedullary rod or fixation member in the intramedullary canal of a tibia wherein the fixation member is anchored to the tibia by means of screws at non-perpendicular angles to one another and to the fixation member (Figs. 1 and 4, col. 3, lines 47-67 and col. 4, lines 1-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the fixation device of Leu et al. in the Karladani et al. method, since it was well known in the art to use such a device for fracture fixation.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karladani et al. and Myers (US 5,624,447), as applied to claim 3, further in view of Wilson et al. (US 6,656,189).

The combination of Karladani et al. and Myers discloses all elements of the claimed invention except for the sheath being made of a radiolucent material and having radiopaque markers.

Wilson et al. teach constructing a guide of a radiolucent material and providing radiolucent pins or markers on the guide to facilitate positioning of the guide (col. 3, lines 57-65 and col. 4, lines 41-55).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the sheath in the device of the method of the combination of Karladani et al. and Myers of a radiolucent material and to have provided radiopaque markers or pins to facilitate positioning of the sheath.

The method steps of claims 8 and 9 are rendered obvious by the above discussion.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Karladani et al. and Myers (US 5,624,447) further in view of Orr (US 5,865,768).

The combination of Karladani et al. and Myers discloses all elements of the claimed invention except for providing a guide pin or wire having a radiopaque marker.

It is very well known to provide radiopaque sections on a guide wire to fluoroscopically monitor insertion of the guide wire, as demonstrated by Orr.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a guide wire having radiopaque sections to fluoroscopically monitor insertion of the reamer in the method of the combination of Karladani et al. and Myers.

The method steps of claim 20 are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on January 14, 2008 have been fully considered.

Applicant's arguments with respect to the rejection of claim 1 under 35 USC 102(b) over Karladani et al. are not persuasive for the following reasons.

Karladani et al. shows the incision starting about a superior medial or lateral border of the patella meeting the claim language. Absent definition of a reference plane, the term "supra patella surgical access site" only requires some portion of the surgical access to be above the patella, and not necessarily completely above the patella.

Regarding the limitation, "patient's leg extended," the Examiner notes, Applicant's are not claiming "a fully extended and unflexed" position. Fig. 2 of Karladani shows a lower portion of the patient's leg extending downward from an upper portion of the patient's leg.

Allowable Subject Matter

Claims 17-18, 23, 41-44 and 47-51 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
April 14, 2008

/Anu Ramana/
Primary Examiner, Art. Unit 3733